UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of	)	
Schering-Plough Corporation, a corporation,	)	
Upsher-Smith Laboratories, a corporation,	)	Docket No. 9297
and	)	
American Home Products Corporation, a corporation	)	

RESPONDENT SCHERING-PLOUGH CORPORATION'S STATEMENT OF THE CASE INVOLVING SCHERING AND ESI-LEDERLE

Pursuant to the Court's Scheduling Order, respondent Schering-Plough Corporation ("Schering") submits this statement of the case with respect to the settlement and license agreement between Schering and ESI-Lederle ("ESI").

A. Introduction

Schering manufactures and sells the brand name drug K-Dur®, a sustained-release potassium chloride tablet. K-Dur® is made in conformity with Schering's Patent No. 4,863,743 (the "'743 patent"), which claims a novel formulation for a sustained-release potassium chloride tablet. The patent is on the coating for the potassium chloride tablets – it is the coating that provides the sustained-release mechanism for the drug. Schering's patent does not expire until September 2006.

In late 1995, ESI notified Schering that it had filed an Abbreviated New Drug Application ("ANDA") seeking approval to market its sustained-release potassium

chloride product as bioequivalent to Schering's K-Dur®. Schering brought a patent infringement suit against ESI, alleging infringement of Schering's '743 patent.

ESI's defense to Schering's patent case was extremely weak. It was undisputed that ESI used the same two chemicals in the coating it put on its tablets that were described in Schering's patent. ESI's defense was that it applied these two chemicals in separate layers, whereas Schering's patent called for a mixture of the two. This defense was questionable to begin with. It was Schering's position that its patent did not only cover a mixture. But ESI's defense was completely undermined when Schering's expert conducted tests showing that the two chemicals in ESI's coating were in fact mixed.

Schering engaged in settlement discussions, nonetheless, at the strong urging of the district judge. The settlement discussions occurred under close supervision of Magistrate Judge Reuter, the magistrate judge designated by the district judge for this purpose. There were five separate settlement meetings with Judge Reuter, and some other correspondence on the subject of settlement as well.

During settlement discussions in Judge Reuter's presence, and between the parties as well, ESI proposed that Schering pay ESI a significant sum of money. Schering rejected this proposal both because its case was so strong and because of antitrust concerns. When Judge Reuter urged Schering to consider ESI's proposals, Schering raised the antitrust issue with Judge Reuter, and brought Charles F. Rule, former Assistant Attorney General in charge of the Antitrust Division, to educate Judge Reuter about the potential antitrust issues raised by a settlement involving payment of money by the patent holder to the generic.

Judge Reuter continued to urge the parties—and particularly Schering, which wanted to try the case—to settle. Eventually, the parties agreed to settle the case by splitting the remaining life of the patent so that ESI would be able to enter the market on January 1, 2004, over two years prior to patent expiration in September 2006. As part of the settlement, Schering ultimately agreed to pay a small sum of money, $5 million, in

connection with the settlement, plus $10 million more in the event that the FDA approved ESI's ANDA by a certain date—an event Schering did not believe would occur.

Schering also obtained from ESI the rights to market two additional products not involved in the litigation. Schering paid ESI $15 million for those rights, and believed that those rights were worth $35 million.

The terms of the settlement were worked out in Judge Reuter's chambers, under his close supervision, on a Friday evening. At his direction, the Schering executive who had decision-making authority was located by cell phone at a basketball game and told that if settlement was not achieved that evening, he would have to appear in the Judge's chambers on Saturday morning. Judge Reuter strongly urged Schering to settle, expressing the view that the amounts of money, which were much smaller than ESI had originally proposed, were reasonable and that any possible antitrust concerns were obviated by his involvement.

The terms of the settlement were written down on a piece of paper in Judge Reuter's chambers, which he reviewed.

Complaint Counsel claims that the settlement agreement harmed consumers, and was anticompetitive. Complaint Counsel does not dispute that Schering would have won the patent case. It does not dispute that Schering's case against ESI was extremely strong and that ESI's defense was weak. Instead, Complaint Counsel bases its case on the purely theoretical proposition that any settlement in which a patent holder pays any money to a generic company is bad for consumers and anticompetitive. That is the theory of Complaint Counsel's economist. The problem with that *theory* is that it is wrong as a matter of *fact*. The settlement brokered by Judge Reuter is very beneficial to consumers and to competition. Judge Reuter caused Schering to let ESI's generic product on the market two and a half years before Schering's patent expires. Consumers will fare much better under the settlement than they would have if the case had gone to trial.

1. Settlements, Generally, Are Beneficial to Consumers

The law strongly favors the settlement of disputes. *See, e.g., D.H. Overmyer Co. v. Loflin*, 440 F.2d 1213, 1215 (5th Cir. 1971) ("Settlement agreements are highly favored in the law and will be upheld whenever possible. . . ."); *In re Sumitomo Copper Litig..*, 869 F.2d 1469, 1473 n.5 (Fed. Cir. 1989) ("The arm's-length compromise of a disputed claim has long been favored by the courts."); *Hartley v. Mentor Corp.*, 869 F.2d 1469, 1473 n.5 (Fed. Cir. 1989) ("[The] position that the courts should favor and enforce settlement agreements is one this panel heartily endorses."). Settlements allow the parties to save huge litigation costs. They permit parties to avoid the distraction of corporate officials that inevitably accompanies litigation. They permit businesses to plan, with some certainty, about businesses' future. And they permit the parties to avoid the risks and uncertainty associated with a trial. All of these cost savings will inevitably be passed on to consumers by American businesses. For these reasons, settlements are much more likely to benefit consumers than the alternative of continued litigation. Moreover, settlements preserve scarce judicial resources, as well. Schering will offer expert testimony from two expert witnesses, one a renowned law professor on the subjects of negotiation and dispute resolution, and the other a practitioner with experience as a litigator and mediator of patent disputes, to support these points.

Schering's experts will also testify that it is commonplace for parties in litigation disputes to explore business transactions involving products or services outside the issues in dispute as a means of reaching common ground. One of Schering's experts has written books advocating parties—and will and will testify that he teaches law students in his negotiation and mediation courses—to search for value-creating transactions going beyond the subject matter of the litigation as a means of facilitating resolution of the dispute.

Finally, Schering's experts will testify that in many cases the payment of some money from one party to another in connection with a settlement is necessary to enable the parties to settle at all. And many such settlements will be procompetitive.

2. The Settlement Was Reasonable and Beneficial to Consumers in Light of Schering's K-Dur® Patent

Complaint Counsel have not alleged, and will not be able to prove, that Schering's K-Dur® patent either was invalid or was not infringed by ESI's potassium chloride product. It is Schering's position that Complaint Counsel must allege and prove that Schering's patent position was not strong enough to warrant the split in the remaining patent life agreed to by the parties. Under the settlement agreement, Schering gave ESI the right to enter the market over two years before Schering's patent expires. This entry date is less than two years later than the earliest date that ESI could have entered had it prevailed in the patent litigation, given Complaint Counsel's position that Upsher was at all relevant times entitled to 180 days of marketing exclusivity. American Home Products Corporation ("AHP"), ESI-Lederle's parent corporation, is exiting the oral generic pharmaceutical business. AHP thus apparently has no plans to market its generic version of K-Dur® – fact which renders moot the most important feature of the relief sought in the complaint.

We believe that Complaint Counsel bears the burden of proving that Schering's patent is invalid or was not infringed, or at least that the split in the patent life does not reflect the objective strength of Schering's position in the lawsuit. But regardless of who bears the burden of proof on these issues, Schering will show that the terms of the settlement were better for consumers than the likely outcome of continued litigation. Indeed, given the overwhelming weakness of ESI's position, the settlement is if anything procompetitive. Schering will offer the testimony of experts on these points as well.

B. Legal and Factual Issues to be Decided by the Administrative Law Judge

1. Whether the ESI/Schering Agreement is Reasonable

The overarching issue to be resolved with respect to the ESI/Schering agreement is whether that agree imposes an unreasonable restraint on competition. That issue is to be analyzed under the rule of reason. *See, e.g., State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997) (most antitrust claims involved an analysis of whether the questioned practice imposes an unreasonable restraint on competition). Courts will depart from this standard inquiry into reasonableness when extensive experience with a specific type of restraint has shown that anticompetitive effects of the restraint almost always outweigh its procompetitive benefits. *See, e.g., Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 UlS> 36, 49-50 & n.16 (1977); *Broadcast Music Inc. v. Columbia Broadcasting Sys., Inc.* 444 U.S. 1, 19-20 (1979); *Khan*, 522 U.S. at 10; *Walker Process Equip., Inc. v. Food Mach. Corp.*, 382 U.S. 172, 178 (1965).

Settlements of intellectual property litigation in particular should be analyzed under the rule of reason. Courts have limited experience in evaluating such agreements, and, as set forth above, settlements provide important procompetitive benefits that must be taken into consideration in any antitrust analysis. *See, e.g., Hartley v. Mentor Corp.*, 869 F.2d 1469, 1473 n.5 (Fed. Cir. 1989); *Speed Shore Corp. v. Denda*, 605 F.2d 469, 473 (9th Cir. 1979); *Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1372 (6th Cir, 1976). The Commission's ongoing generic drug competition industry survey, designed to provide the Commission with more information about these types of agreements, demonstrates that it currently lacks sufficient experience in analyzing patent infringement settlement agreements to condemn any particular one as unreasonable *per se*.

2. Whether Schering's Patent Was Invalid or Infringed by ESI's Product, or Whether the Split in the Patent Life Under the Settlement Does Not Reflect the Strength of Schering's Position in the Lawsuit

In order to determine whether the ESI/Schering settlement was reasonable, the Court will have to determine whether Schering's patent gave it the legal right to exclude ESI from the market altogether. If it did (*i.e.*, if Schering's patent was valid and infringed), then no consumer harm could result from a settlement that permits ESI to market its product before patent expiration. Put another way, the Court must compare the effect on consumers of the settlement agreement to the "but for" world of continued litigation. If the settlement (*i.e.*, the split in the remaining patent life) reflects the objective strength of the parties' positions in the underlying patent litigation, then no consumer harm can result from a settlement that permits ESI to market its product at a time that reflects its chances in prevailing in the litigation. The court will then have to determine whether Schering's eventual concession—which occurred after the split in remaining patent life had been agreed to—to pay a small sum of money to ESI in connection with the settlement was a payment in exchange for an agreement to delay entry. Schering will prove that the amount of money was only a very small fraction of the sales volume of the products at issue in the litigation. And as set forth above, Schering will prove that, given ESI's extremely poor chances in the litigation, consumers are indisputably better off under the settlement than they would have been had the litigation continued.

3. Whether Schering is Immune from Antitrust Liability in Light of the Court's Active Involvement in and Supervision of the Settlement

The court will have to determine whether Schering can be held liable under the antitrust laws for engaging in a settlement agreement when the terms of that agreement were known to and urged on Schering by a magistrate judge acting at the direction of the

district court. Moreover, the Court will have to determine whether Schering can be held liable for entering into an agreement involving the payment of money from Schering to ESI, when the magistrate judge was made expressly aware of the antitrust issues potentially implicated by such a settlement.

4. Whether the ESI/Schering Settlement Prevents ESI from Marketing Non-infringing Products

The Complaint alleges that the ESI/Schering settlement prevents ESI from marketing not only its generic K-Dur®, but also from marketing other similar products that did not infringe. The analysis of this issue will require an evaluation of whether Schering intended to prevent only the marketing of products that presented substantially the same infringement issue as ESI's generic K-Dur® product. It will also require the Court to determine whether ESI had the ability and intent to manufacture a non-infringing product that would compete with K-Dur®.

5. Whether the Matter is Moot

As part of the relief requested in this matter, the complaint seeks an order requiring Schering to "immediately license for no compensation its '743 patent to . . . ESI so as to allow [ESI] to make, produce, and market commercially generic versions of Schering's K-Dur 20 and K-Dur 10." Complaint, Notice of Contemplated Relief ¶ 5. Pursuant to the terms of the settlement, ESI will be permitted to enter the market over two years before expiration of Schering's patent. AHP, however, has decided to exit the oral generic pharmaceutical business. Thus, AHP is apparently unable to implement the principal feature of the prospective relief sought by Complaint. This would seem to make the matter moot.

C. Status of Compliance With Discovery

Schering produced approximately 100 boxes of materials during the year-and-a-half investigation of this matter. Schering is in the process of producing documents in response to Complaint Counsel's post-complaint requests. These include approximately

20 boxes of documents that will be produced by the end of this week related to Schering's ezetimibe. Schering is negotiating with Complaint Counsel regarding Complaint Counsel's very broad requests for documents related to licenses and evaluations of other products not involved in the Upsher or ESI settlements.

Schering continues to produce documents in response to Complaint Counsel's document requests, and has reached agreements with Complaint Counsel regarding dates for compliance with certain of those requests.

Complaint Counsel has taken a number of Schering depositions in this litigation and the pre-complaint investigation. Schering is continuing to work with Complaint Counsel to schedule additional depositions requested by Complaint Counsel.

Schering served requests for documents on Complaint Counsel on or about June 19, 2001. Complaint Counsel has produced certain materials gathered during its lengthy investigation of this case, and has produced about two boxes of documents in response to Schering's document requests.

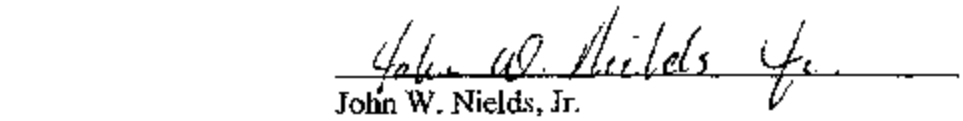
In early June 2001, Schering filed a Freedom of Information Act ("FOIA") request with the Food and Drug Administration ("FDA") for certain documents. While FDA has not yet produced any documents in response to the request, Schering continues to work with FOIA staff at FDA to obtain such materials.

Schering has issued a number of interrogatories to Complaint Counsel. Most of these are "contention" interrogatories that ask Complaint Counsel whether it is taking certain positions and, if so, what facts on which intends to rely at the hearing in support of them. Complaint Counsel has for the most part declined to state what facts it intends to rely upon, on the ground that it is premature to do so before the close of discovery.

D. Status of Settlement Negotiations

There are no ongoing discussions between Schering and Complaint Counsel regarding the settlement of this matter. Schering remains willing to confer with Complaint Counsel in good faith regarding a negotiated resolution of this case.

Respectfully submitted,



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Dated: September 18, 2001

Attorneys for Respondent
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CERTIFICATE OF SERVICE

I hereby certify that this 18th day of September, 2001, I caused an original, one paper copy and an electronic copy of the foregoing Respondent Schering-Plough Corporation's Statement of the Case Involving Schering and ESI-Lederle to be filed with the Secretary of the Commission, and that two paper copies were served by hand upon:

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